Instructions for Use en

bite away two

A medical device for symptomatic thermotherapeutic *treatment of itching and pain caused* by insect stings *and bites*

fast | effective | well-tolerated

Overview of all benefits
- Fast and reliable relief from itching and pain caused by insect bites, without tedious application of creams and ointments
- Well tolerated – bite away® two works without chemicals and is therefore suitable for children from the age of 3, pregnant women and, due to the ceramic contact surface, for allergy sufferers
- *Mute function for silent treatment of insect bites in the night*
- Can optionally be used with either non-rechargeable or rechargeable batteries
- Patented multi-level safety features:
  1. Intelligent temperature control
  2. Independent temperature guard
  3. Fail-safe overheating protection

Please read the entire instructions for use carefully before the first application and follow the instructions and warnings.

bite away two

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Intended use

bite away® two is a patented thermotherapeutic medical device for topical symptomatic treatment of itching and pain caused by insect stings and bites, for example by mosquitoes, wasps, bees, hornets or horseflies.

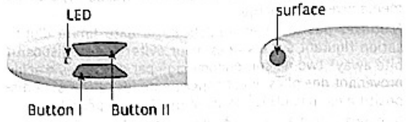
If the device is applied immediately after the sting/bite, the symptoms can usually be prevented completely which is why the affected site on the body should be treated as quickly as possible. Even if the device is applied slightly later, accompanying symptoms such as itching and pain can be effectively relived and can subside sooner.

How it works

The application of concentrated heat (local thermotherapy) is a physical mode of action based on the application of a brief, concentrated thermal stimulus to a small, limited area of skin. This localised pulse of heat may be sufficient to trigger a response from the body that reduces itching and pain.

Application

Design of bite away® two:



Initial commissioning:

The packaging of bite away® two includes two AAA LR03 1.5 V batteries. The device is delivered with the batteries inserted. You can start to use it straight away.

Treatment:

bite away® two is very simple to use:
- Place the ceramic contact surface of the device onto the sting or bite (remove the stinger first if necessary) and gently press it against the skin.
- Then select the treatment duration by pressing the corresponding button:
  - ● 3 seconds (button I) for the initial treatment and for people with sensitive skin
  - ●● 5 seconds (button II) for a regular application.
- The heating phase starts after the corresponding button is pressed. During the heating phase, the ceramic contact surface heats up to a temperature of approximately 51 °C. As soon as this temperature is reached, treatment starts. The LED lights up during treatment. The device switches off automatically at the end of the chosen treatment duration. An additional acoustic signal sounds at the start of the heating phase and at the end of treatment.
- Remove the device from the area of skin treated.

If necessary, the same insect sting or bite can be treated several times. Please leave a treatment interval of at least 2 minutes between each application when treating the same sting or bite. Immediate subsequent treatment of another insect sting or bite on a different skin area is possible without any problems after the first treatment with bite away® two.

Directions for use

Please remove any insect stings remaining in the skin before using bite away® two.

bite away® two is intended for self-administration by adults and children from 12 years of age.

For children under 12 years of age, the device should only be used with adult supervision.

Person with a limited ability to perceive the visual or acoustic signals of the device should be assisted by an adult when using the device.

Children under 7 years of age are often not yet able to understand the connection between a short heat treatment and its positive benefits. Please therefore check carefully whether symptomatic treatment with bite away® two is suitable for your child. Please also bear in mind that children's skin is still developing and, thus, can react more sensitively to heat stimuli.

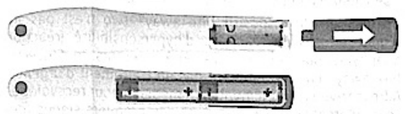
Do not use the device in children under 3 years of age.

Cleaning and disinfection:

All external surfaces of the device can be cleaned with a soft cloth that has been slightly moistened with water. If the device is obviously contaminated, it must be cleaned. To do this, please use a soft cloth that has been moistened with 70% isopropanol. Wipe all external surfaces thoroughly until no more contamination is visible. Then dry these surfaces with a cloth.

The ceramic contact surface must be disinfected before the device can be used by another person. To do this, moisten a soft cloth well with 70% isopropanol or use a conventional disinfecting cloth based on 70% isopropanol. Wipe the ceramic contact surface thoroughly with this cloth for 30 seconds. Allow the surface to air dry.

Changing the batteries:



bite away® two can be used with either non-rechargeable or rechargeable batteries.

To change the batteries, open the battery cap by pressing the battery cap at the mark and simultaneously push it in the direction of the arrow (see figure). Remove both discharged batteries. Insert the new batteries into the device according to the marks (see figure). When doing so, observe the indicated polarity of the batteries. After inserting the batteries, push the battery cap on fully.

When the batteries need to be replaced, the LED will flash 3 times and the acoustic signal will sound 3 times.

Please use batteries of type AAA LR03, HR03 or HR11/45 with a voltage of 1.2 V to 1.5 V. Please note that using rechargeable batteries with a voltage of 1.2 V may result in a lower number of applications per battery charge.

Muting:

If required, the acoustic signals can be switched off (muted). To activate or deactivate the mute function, press and hold both buttons simultaneously for 3 seconds. The switch to the corresponding mode is indicated by the following signals:

LED flashes 2 x	Mute function activated
LED flashes 2 x acoustic signal 2 x	Mute function deactivated

Please note that not all errors can be muted (for details, see the table "Signals and troubleshooting").

Signals and troubleshooting:

LED flashes 3 x acoustic signal 3 x	– Treatment temperature was not reached. – Batteries too low: Change the batteries (see section "Changing the batteries").
LED flashes 5 x acoustic signal 5 x (sounds also during mute)	– Malfunction: The cause can be incorrect use, e.g. triggering and operating the device against air. – If this error message occurs repeatedly despite proper use, please contact the manufacturer or distributor of bite away® two.
bite away® two does not heat up/ does not work	– Change the batteries (see section "Changing the batteries"). – If this error message occurs repeatedly despite fully charged batteries, please contact the manufacturer or distributor of bite away® two.

Warnings

bite away® two must not be used on or in
- anaphylactic reaction
- eyes or eyelids
- mucous membranes
- open wounds, damaged skin (e.g. blisters)
- scalded or burnt skin
- frostbite
- tumours and malignant changes of the skin
- known increased algesia (increased pain sensation) in small fibre neuropathy, allodynia, hyperalgesia
- people with known limited sensitivity to pain and temperature.

bite away® two is not indicated in case of hypersensitivity reactions (anaphylactic reaction) after an insect sting or bite. bite away® two is not a substitute for emergency treatment. You should immediately call a doctor at the first signs of any such reaction (e.g. increased itching, reddening, swelling or formation of a welt; dizziness, nausea, difficulties breathing, hypotension or hypertension).

Medical advice should be sought in the following cases:
- if symptoms persist when using bite away® two.
- if symptoms worsen when using bite away® two. Until these have been clarified, you should stop using the device.
- tick bites, as bites of these arachnids can cause the transmission of pathogens such as Lyme disease or tick-borne encephalitis (TBE).

bite away® two can neither avoid nor prevent the transmission of pathogens through insect bites or stings. Medical advice should be sought if there is an indication of an illness transmitted by an insect sting or bite.

Furthermore, the device must not be used immediately after the application of ointments, creams, lotions and other preparations on the skin area to be treated as possible interactions with ingredients of these products cannot be ruled out.

In individual cases, the treatment temperature may cause some discomfort.

On sensitive skin, a temporary reddening of the skin may occur after use. In very rare cases, skin irritation may occur in users with a sensitive skin type.

Do not use the device in case of damage, obvious malfunction or with open housing. Do not use damaged or wet batteries. Protect the device from moisture.

Any changes to bite away® two are not permitted.

Keep the device out of the reach of children.

When using bite away® two, please note it contains small parts that can be swallowed by children under 3 years of age and these pose a choking hazard.

Permissible environmental conditions

Store the device protected from direct sunlight, in a dry and clean place.

Please observe the following permissible environmental conditions:

	Temperature [°C]	Relative humidity [%]	Air pressure [hPa]
Operation	5 to 40	15 to 85	700 to 1060
Transport*			
Storage*			

* Please note that the manufacturer of the batteries may have stated different storage conditions.

Please observe the handling instructions on the batteries you use. Only combine batteries of the same type and state of charge.

Do not use the batteries beyond the expiry date stated on them. To prevent the risk of damage to bite away® two due to leaking battery acid, remove the batteries from the unit if it is not going to be used for an extended period of time.

bite away® two has an expected service life of at least 5 years.

Remove the used batteries and dispose of them according to the local regulations for the disposal of batteries.

The device must not be disposed of in household waste. Dispose of the device according to local regulations for disposal of waste electrical equipment.

Manufacturer:
mibeTec GmbH
Münchener Straße 15
06796 Brehna
Germany
e-mail: contact.mibetec@dermapharm.com
www.bite-away.com

Please contact the manufacturer or distributor if you have any questions about the product or how it works.

Please report any serious incident that has occurred in relation to bite away® two to the manufacturer and the competent authority in your country.

Date of revision of the text: 2024-09

CE 0123

Follow the instructions for use (blue/white)

MD Medical device

Protect the device from direct sunlight and store in a dry place/protect from moisture

Permissible environmental temperature

Permissible air pressure

Permissible relative humidity

UDI Unique device identification

REF Catalogue number

Date of manufacture

LOT See device for batch number

Do not dispose of with household waste/dispose according to local regulations for disposal of waste electrical equipment

Technical data:

Suitable types of batteries: AAA LR03 or HR03 or HR11/45 with 1.2–1.5 V

The ceramic contact surface is a type BF applied part in accordance with EN 60601-1

IP42: Protected against ingress of solid objects (1 mm) and against dripping water when tilted

Mute function for silent treatment of insect stings and bites

2 x AAA LR03 1.5 V batteries included in the package

3+ Suitable for children from 3 years

Suitable for pregnant women

Suitable for breastfeeding women

This medical device complies with the EMC standard IEC 60601-1-2:2014+A1-2:2020.

Nevertheless, special precautions should be taken:

bite away® two is intended for use in home healthcare environment.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of bite away® two, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

According to the specifications of IEC 60601-1-2:2014+A1:2020 the technical description can be requested in digital form in the English or German language from mibeTec GmbH (address can be found under "Manufacturer").